

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 21, 2020

David Swain
Authorized Agent for Strategic Resource Optimization, Inc.
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street
Columbia City, Indiana 46725

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: ELECTRO-BIOCIDE EPA Registration Number: 87492-1 Application Date: March 20, 2020

Decision Number: 561528

Dear Mr. Swain:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are large non-enveloped and enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 37 (ATCC VR-1147) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

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Enclosure: stamped label

ELECTRO-BIOCIDE

[ELECTRO-BIOCIDE is a multi-purpose, bactericidal and †virucidal cleaner that disinfects pre-cleaned hard, non-porous surfaces]

ACTIVE INGREDIENT:	
Chlorine Dioxide	
OTHER INGREDIENTS:	99.98%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 87492-1 EPA Est. No. 85056-CO-001

Net Contents: 1 gallon

Manufactured for:

Strategic Resource Optimization Inc. (SRO) 289 Elk Creek Drive Bailey, CO 80421

[PRODUCT OF THE USA]

Expiration Date: See sticker attached to container for expiration date. {Expiration Date is 15 days from date of manufacture}

ACCEPTED

04/21/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87492-1

Recommended Use (Locations):

ELECTRO-BIOCIDE is a multipurpose bactericidal and †virucidal cleaner that disinfects pre-cleaned hard non-porous surfaces such as stainless steel, chrome, glass, plastic, vinyl, glazed porcelain, glazed ceramic, plastic laminate, sealed terrazzo or granite, linoleum, metal, and finished wood. Recommended for use in:

Hospitals Schools
Nursing Homes Universities
Health Care Settings Gymnasiums
Hotels & Motels Locker Rooms
Cruise Ships Restrooms
Dormitory Rooms Fitness Centers

Temporary Housing

Households

Public Transportation

Recommended Use (Surfaces):

ELECTRO-BIOCIDE disinfects and is bactericidal and [†]virucidal on the following precleaned hard nonporous surfaces such as stainless steel, chrome, glass, plastic, vinyl, glazed porcelain, glazed ceramic, plastic laminate, sealed terrazzo or granite, linoleum, metal, and finished wood when used as directed:

Call bell Patient Equipment
Over bed tables Restroom Fixtures
Side tables Trash cans

Closets Shelves Drawers Telephone TV remote Floors Walls

For Use as a Disinfectant and †Virucide:

Disinfectant: ELECTRO-BIOCIDE, when [used as directed] is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Staphylococcus aureus* (MRSA) and *Enterococcus faecalis* (VRE) with a 10 minute contact time on pre-cleaned hard non-porous inanimate surfaces.

[†]Virucidal: ELECTRO-BIOCIDE, when [used as directed] is effective against Rhinovirus Type 37, Influenza Type A (H1N1) Virus, Hepatitis A Virus and Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS virus] with a 10 minute contact time on pre-cleaned hard non-porous inanimate surfaces.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

TO DISINFECT:

- 1) Only trained applicators are permitted to apply this product.
- 2) Handlers applying chlorine dioxide in an occupational setting must wear gloves.
- 3) Pre-clean all hard, non-porous surfaces with ELECTRO-BIOCIDE or detergent prior to disinfection
- 4) Spray from 4-6 inches all pre-cleaned hard, non-porous surfaces until surface is thoroughly wet
- 5) Allow surfaces to remain wet for 10 minutes
- 6) Allow surfaces to air dry

[NOTE: Pre-treat a small, inconspicuous area of surface being disinfected for colorfastness.]

*KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 [AIDS Virus] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of ELECTRO-BIOCIDE.

Contact Time: Allow surface to remain wet for 10 minutes to kill HIV-1. Use a 10 minute contact time for all other organisms claimed.

Note to Agency: Text appearing in parenthesis () or brackets [] is optional text. {Bracketed text} is for administrative purposes only and will not appear on final printed label.

Disposal of Infectious Material: Blood / body fluids must be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE:

Store this product in a cool, dry area, away from direct sunlight or heat. Always store pesticides in the original container. In case of leaking container, wrap product in secondary container and follow pesticide disposal instructions. In case of spill, contain and flush with water and dispose of waste on site.

PESTICIDE DISPOSAL:

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Call your local solid waste disposal agency or 1-800-CLEANUP for disposal instructions.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or dispose in trash.

{Emerging Viral Pathogens}

{This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.}

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus type 37 (ATCC VR-1147)
Large, non-enveloped virus	Rhinovirus type 37 (ATCC VR-1147)

Electro-Biocide has demonstrated effectiveness against viruses similar to {Insert name of emerging virus} on hard, nonporous surfaces. Therefore, Electro-Biocide can be used against {Insert name of emerging virus} when used in accordance with the directions for use against Rhinovirus type 37 (ATCC VR-1147) on hard, nonporous surfaces. Refer to the CDC -or- OIE website at {Insert pathogen-specific website address} for additional information.

{Insert name of illness/outbreak} is caused by {Insert name of emerging virus}. Electro-Biocide kills similar viruses and therefore can be used against {Insert name of emerging virus} when used in accordance with the directions for use against Rhinovirus type 37 (ATCC VR-1147) on hard, nonporous surfaces. Refer to the {CDC -or- OIE} website at {Insert pathogen-specific website address} for additional information.